

## STATE OF VERMONT

## HUMAN SERVICES BOARD

In re ) Fair Hearing No. 17,573  
 )  
Appeal of )

# INTRODUCTION

The petitioner appeals a decision by the Department of Prevention, Assistance, Transition, and Health Access (PATH) denying her reimbursement for OxyContin tablets under the Medicaid program.

## FINDINGS OF FACT

1. OxyContin is a synthetic morphine which is in the compendium of drugs approved by the Federal Drug Administration and which, prior to last summer, was regularly covered by the Medicaid program without prior approval. On July 10, 2001, the governor announced that the drug would be restricted due to information showing that there was an increase in diversion and abuse of this drug. On July 23, 2001, the Medical Director of the Office of Health Access (who was not involved in the policy decision) notified all Medicaid providers by letter that prior authorization would be required for this drug beginning August 1, 2001. Attached to the letter was a prior authorization form to be used for that

purpose. Authorization was limited to persons diagnosed with sickle cell disease or cancer and those with severe pain being treated under management of an approved pain management clinic.

2. On August 1, 2001, additional letters were sent out by the clinical unit supervisor of the Office of Vermont Health Access of PATH to all high volume prescribers of this medication indicating that August 13, 2001 would be the effective date of the policy limiting OxyContin to prior authorization status. Letters were also sent to all Medicaid participating pharmacies with the same information

3. A report was prepared by the Vermont Medical Society on September 6, 2001, complaining, among other things, that the new restrictions had been implemented too quickly and that many physicians, nurses, pharmacists, hospices and nursing homes were not made adequately aware of the new requirement in advance of its imposition and had experienced difficulty with the program. There was also concern that PATH's standards in requiring review diverged from the FDA drug approval guidelines and that treatment through pain management clinics was unrealistic for rural Vermonters.

4. The chair of the Health Access Oversight Committee in the state Senate sent a letter to the Commissioner on

September 17, 2001 expressing a concern that the new policy was implemented without adequate input from physicians with expertise in pain management and echoing some of the concerns of the medical society. It also recommended that PATH undertake the appropriate education of prescribers, pharmacists and patients prior to implementation of any new prior approval policy.

5. The Commissioner of PATH responded to this concern in a letter dated October 3, 2001 defending the Department's action but noting that the Prior Authorization Request form had been revised "to reduce the confusion and misunderstanding that resulted from its specific reference to sickle cell anemia and cancer." The letter also acknowledged that "the prior authorization process for OxyContin went into effect quickly and there was a confusion about whether patients with legitimate needs for effective pain medication would get proper care." The Commissioner noted that there would be a meeting scheduled among "all affected interests" to discuss the Preferred Drug List, outline the steps of the proposed prior authorization process, and obtain public input on implementing the program."

6. In the midst of this confusion and controversy, the petitioner had a medical emergency for which her doctors

prescribed OxyContin. The petitioner has a disc disease which has resulted in a number of herniated and ruptured discs that have required surgical intervention. On September 8, 2001, the petitioner was admitted to the emergency room in great pain due to yet another slipped disc. The emergency room physician prescribed a small amount of OxyContin for relief of the pain. The petitioner was released from the emergency room but was in urgent need of surgery which she set about arranging.

7. On September 8, 2001, the petitioner's went to her usual pharmacy to fill her pain prescription. She recalls that she was told by one of the pharmacists or assistants that the Department was not covering this medication but that receipts could be submitted for reimbursement. The petitioner paid cash for this small number of pills, at a cost of \$37.49. She did not call PATH at that time as she was too distracted preparing for her departure for New York City for her emergency medical consultation which was to occur in two days. She was too confused to question what she thought she had been told at the pharmacy. The pharmacist apparently did not call the prescribing physician at this time to notify him that he needed to obtain prior approval for the medications, as is his usual procedure in these cases.

8. Her physician in New York set up her surgery for October 16, 2001. When she returned to Vermont on September 17, 2001, a physician covering for her usual doctor wrote a prescription for 8 OxyContin pills until she could get another appointment with her regular physician. The petitioner had that prescription filled on September 19, 2001 and paid for it herself at a cost of \$30.79. Again, it does not appear that on this date that anyone at the pharmacy called her physician to advise him of the prior authorization requirement for Medicaid coverage of this medication or explained the requirement to her.

9. The petitioner's primary physician wrote her a prescription on September 21, 2001 for 60 tabs of OxyContin to alleviate her pain until her surgery date. His nurse testified that although not all of the mail had been opened due to a leave by the physician, she could not recall seeing anything about OxyContin prescriptions and was unaware that they required prior approval. She had no idea how to request prior approval since it had never been needed before for any services provided by her office. She had no forms on which to request OxyContin. The practice does not prescribe a lot of OxyContin and has few adult Medicaid beneficiaries.

10. The petitioner had the prescription filled and paid for these tablets herself, planning to submit the bills for reimbursement when she felt more physically able to cope with it. Because the cost of the prescription was \$197.99, she did not make her car payment that month to buy the medications. Again it does not appear that on this date the pharmacy notified her physician of the need to request prior authorization for this medication or explained the need to the petitioner.

11. The petitioner had extensive back surgery on October 16, 2001 in New York. She came back to Vermont and on October 21, 2001 had a friend take in her last prescription written by a doctor in New York for OxyContin because she was unable to go to the pharmacy herself. The friend recalls that the petitioner told him that he needed to save the receipt so it could be submitted to Medicaid later.

12. When the friend got to the pharmacy, however, he was told by the pharmacist that the drug needed to be "prior approved" and that he would call the physician. That is the information which the pharmacist said should have been routinely given to the petitioner when she presented her first script. He personally would never have told her to save her receipts for future reimbursement. However, he does not

recall dealing with the petitioner personally on this matter during her prior visits and no finding can be made that the appropriate advice did occur during the prior visits. On this occasion (October 25, 2001), the pharmacist called her Vermont physician to see if he could rewrite the script for her because it was an out of state prescription. He forgot to tell the physician that he had to request prior approval for this drug as well. The petitioner needed the medication without delay and borrowed money from her parents to pay it, some \$355.99. She wants to reimburse her parents for that expense.

13. At some point, the pharmacist did contact the physician about prior approval, it was sought by her doctor with a form provided by a legal aid organization and was finally approved. The petitioner continued to take the medication which was thereafter paid for by Medicaid until the middle of November of 2001. She has had no further need for the medication since that time.

14. The petitioner's credible testimony in this matter is that during the period at issue, she was distracted by pain and absorbed in the process of arranging for and attending urgent surgery in another state. She was too exhausted and confused to investigate why her medication was not being

covered. She trusted what she understood the pharmacist was saying and figured she would submit all her bills later when she was able to concentrate on that activity. She did not question anything because she was not able to function at a very high level. The petitioner points out that her own confusion was compounded by the confusion of three Vermont doctors who, although they knew she was a Medicaid recipient, failed to realize that they needed to request prior approval for this medication as well. No one ever notified her personally as a Medicaid recipient that she needed to obtain prior approval for this medication.

#### ORDER

The decision of the Department is reversed.

#### REASONS

Regulations adopted by PATH implementing the federal-state Medicaid program provide that:

Payment may be made for any preparation, except those unfavorably evaluated, either included or approved for inclusion in the latest edition of the official drug compendia: the U.S. Pharmacopoeia, the National Formulary, the U.S. Homeopathic Pharmacopoeia, AMA Drug Evaluations, or Accepted Dental Therapeutics. These consist of both "legend" drugs, for which a prescription is required by State or Federal law, and "over-the-counter" medicinals, normally purchasable without a



prescription. The only exceptions to this are specified in Sections M811.1 to M811.4.

Medicaid Manual § 810

The sections referred to above include smoking cessation products, non-drug items, amphetamine, appetite depressants, vitamins, minerals and certain classes of over-the-counter medications. See M811.1 to 811.4. There is no dispute between the parties that OxyContin is approved by the FDA and listed in the compendia of approved drugs cited above.

PATH also has regulations which authorize it to require prior approval of payment for a service in order to "assure the appropriate use of health care services." M106.1. Prior approval may be required for payment of a service when it meets certain specific criteria including "questionable medical necessity", the need to monitor use to "manage the expenditure of program funds" and "to prevent the continuation of the service when it ceases to be beneficial." M106.2. The regulations require that:

The complete and current list of all services and items including procedure codes that require prior authorization is set out in the Provider Manual. The list is updated periodically. Additions and deletions to the list are also published in advance in the provider advisory newsletter and other communications to providers.

M106.2

PATH has invoked the provisions of M106.2 to place OxyContin on the list of drugs which require prior approval. It certainly made attempts to provide notice to providers that this change had been made as it is required to do by its regulation. It also attempted to notify the providers "in advance" of this action although it appears that many providers did not feel that the "advance notice" period (about three weeks) was sufficiently long for changes in procedures to be implemented in an orderly way for their patients. Others, including the petitioner's three physicians, did not recognize the need for Medicaid approval for this drug even though directives had been sent out some six to twelve weeks before the medication was prescribed.

The petitioner argues that she should not have been required to pick up \$688.54 for medications which PATH subsequently agreed that she needed because her providers (three physicians and at least one pharmacist) were not yet acquainted with the new prior approval requirement for this drug and the method for obtaining it. There is a great deal of justice in her argument since the petitioner herself as a Medicaid recipient was never notified by anyone of the need for prior approval or the method for obtaining it.

However, it is not necessary to delve into the equities of this situation since the Department has a regulation which allows "waiver" of the prior approval process in an emergency medical situation:

The department shall waive the requirement that a covered service receive prior authorization if, in the department's judgment, the service provided without prior authorization meets one or both of the following circumstances.

- The service was required to treat an emergency medical condition.
- The service was provided prior to the determination of Medicaid eligibility and within the retroactive coverage period.

M 106.4

The Department has made no judgment with regard to the emergency nature of this request. Since it has not applied this waiver criteria, it is up to the Board to determine if it applies. The facts of the petitioner's situation show that she was in a crisis situation based on the sudden onset of a serious back condition. The emergent nature of her problem and the pain and confusion it caused her more than excuse her researching the causes and solutions for the problems she was encountering with payment of prescribed medications during this confusing transition period. Since the Department agrees that she did need this medication, the fact that she was in an

emergency medical condition and could not be assisted by her uninformed providers more than justifies a waiver of the prior authorization in this instance. The Department should be required under its own regulation to reimburse the petitioner for the cost of the OxyContin she paid for herself before formal authorization was sought.

# # #

Board Member Stoneman voted to cover all but the October 25, 2001 prescription based on his view that no emergency medical condition existed on that date.